



Pesticide Fact Sheet

Name of Chemical: Fenazaquin
Reason for Issuance: Import Tolerance
Date Issued: August 2007

Description of Chemical

Common Name	Fenazaquin
Chemical Name:	4-tert-butylphenethyl quinazolin-4-yl ether (IUPAC) 3-[2-[4-(1,1-dimethylethyl) phenyl] ethoxy] quinazoline (CAS)
Trade Names:	Pride® , Magister®
EPA Chemical Code:	044501
Chemical Abstracts Service (CAS) Number:	120928-09-8
Chemical Class:	Quinazoline
Registration Status:	No Registered Products
Pesticide Type:	Miticide and Insecticide
Mode of Action:	Disrupt biochemistry of insect mitochondria
Route of Exposure:	Ingestion and Dermal
Producer:	Pentagon Fine Chemicals (England)

Use Pattern and Formulations

Fenazaquin belongs to the quinazoline class of chemicals and is a pesticide intended to control mites and insects (especially whiteflies). Its route of exposure is ingestion and dermal, and its mode of action is the disruption of the biochemistry of insect mitochondria.

In 2005 countries throughout Europe, North Africa, the Middle-East, Asia, and in Latin America had approved its use on pome and citrus fruits. The majority of usage (>80%) is in Europe. Table 1 provides a general summary of the use directions for apples, pears and citrus fruits. The Agency also received a label for a 200 g/L FIC formulation from the U.K., with use directions for apples. This U.K. label specifies a maximum use rate of 150 g ai/ha on apples with a 30-day PHI.

Table 1. Summary of Directions for Use of Fenazaquin.						
Applic. Timing, Type, and Equip.	Formulation [g ai/L]	Applic. Rate (g ai/ha) [lb ai/A]	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (g ai/ha) [lb ai/A]	PHI ¹ (days)	Use Directions and Limitations
Apples/Pears ²						
Early to late season foliar application ³ ; ground equipment	200 g/L FIC	100-250 [0.09-0.22]	1	250 [0.22]	28	Only a single application is allowed per calendar year
Citrus Fruits (Oranges, Mandarins, Lemons) ⁴						
Early to late season foliar application; ground equipment	100 g/L EC 200 g/L FIC	100-450 [0.09-0.40]	1	450 [0.40]	21	Only a single application is allowed per calendar year

¹ The PHIs listed are the minimums allowed in any country; longer PHIs are required in some countries.

² Fenazaquin is reportedly approved for use on apples and/or pears in the following countries: Algeria, Argentina, Azerbaijan, Bulgaria, Chile, China, Croatia, Cyprus, Czech Rep., France, Germany, Greece, Hungary, Israel, Italy, Jordan, Korea, Lebanon, Macedonia, Morocco, Peru, Poland, Portugal, Romania, Russia, Slovakia, Saudi Arabia, Serbia, Slovenia, South Africa, Spain, Switzerland, Taiwan, Turkey, United Kingdom, Uzbekistan, and Yugoslavia.

³ Apply after petal fall.

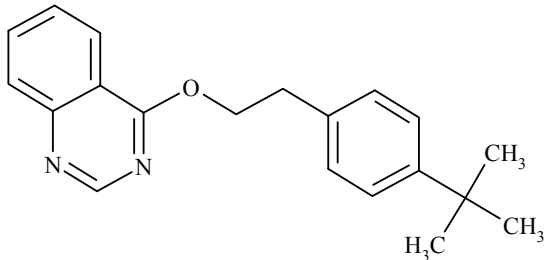
⁴ Fenazaquin is reportedly approved for use on citrus in the following countries: Chile, China, Greece, Italy, Korea, Morocco, South Africa, Spain, Taiwan, and Turkey.

Science Findings

Product chemistry data supporting the use of fenazaquin are summarized below.

1. Physical/Chemical Structure and Nomenclature:

Table 2 presents the structure and nomenclature of fenazaquin below.

Table 2. Fenazaquin Nomenclature.	
Compound	
Common name	Fenazaquin
Molecular weight	306.4
Company experimental names	XDE-436, EL-436, XRD-562, DE-436
IUPAC name	4-tert-butylphenethyl quinazolin-4-yl ether
CAS name	4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline
CAS registry number	120928-09-8
End-use products (EP)	100 g/L EC (MAGISTER [®] 100 EC) 200 g/L FIC (MAGISTER [®] 200 SC and MATADOR [®] 200 SC)

2. Physical and Chemical Properties

Table 3 presents the physicochemical properties of fenazaquin below.

Table 3. Physicochemical Properties of Fenazaquin.					
Parameter	Value				Reference
Melting point/range	77.5-80°C				Evaluation on Fenazaquin, Issue No. 150, Pesticides Safety Directorate, Depart. for Environment, Food, and Rural Affairs, U.K., March 1996
pH	Not determined due to low solubility				
Relative Density	1.16 at 21°C				
Water solubility (20°C)	0.102 mg/L at pH 5 & 7 0.135 mg/L at pH 9				
Solvent solubility (g/L at 23°C)	acetonitrile	33-50	acetone	400-500	
	n-chlorobutane	>500	chloroform	>500	
	dichloromethane	>600	ethyl acetate	400-500	
	dimethylformamide	300-400	ethylene glycol	<5	
	hexane	33-50	isopropanol	50-100	
	methanol	50-100	toluene	>500	
	N-methyl-2-pyrrolidone >500				
Vapor pressure (25°C)	1.9 x 10 ⁻⁵ Pa				
Dissociation constant, pK _a	2.44				
Octanol/water partition coefficient, Log(K _{OW})	5.71 at 25°C; 5.51 at 20°C				
UV/visible absorption spectrum	Not available				

3. Toxicology Summary

Table 4a and 4b lists toxicity studies that the applicant has submitted. These include an acute oral study and subacute, chronic, carcinogenicity, developmental and mutagenicity studies.

Table 4a. Acute Toxicity Data – Fenazaquin Technical			
Study/ Species	MRID	Results	Toxicity Category
870.1100 Acute Oral (Rat)	46684003	LD ₅₀ = 134/138 mg/kg (male/female)	II
870.1200 Acute Dermal, Rabbits	N/A		
870.1300 Acute Inhalation, Rats	N/A		
870.2400 Primary Eye Irritation, Rabbits	N/A		
870.2500 Primary Skin Irritation, Rabbits	N/A		
870.2600 Dermal Sensitization, Guinea pig	N/A		

Table 4b. Subchronic, Chronic and Other Toxicity Profile - Fenazaquin Technical			
Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100	90-Day oral toxicity (rat) (Fischer 344 from Charles River Laboratories Inc., Wilmington, MA)	45029904 (1992) Acceptable/guideline 0, 15, 45, 150, or 450 ppm M: .0, 1.0, 3.0, 9.6, and 28.7 mg/kg/d F: 0.0, 1.2, 3.5, 11.5, and 33.0 mg/kg/d	NOAEL = 9.6 mg/kg/day LOAEL = 28.7 mg/kg/day based on decreased body weight, body weight gain, and food consumption.
870.3100	90-Day oral (gavage) toxicity (rat) (Fischer 344 from Charles River Laboratories Inc., Wilmington, MA)	45029905 (1992) Acceptable/guideline 0, 1, 3, 10, or 30 mg/kg/day	NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on decreased body weight, body weight gain, and food consumption/efficiency.
870.3100	90-Day oral toxicity (hamster)	45029903 (1992) Acceptable/guideline Males: 0, 5, 25, 75, or 150 mg/kg/day Females: 0, 5, 25, 50, or 100 mg/kg/day	NOAEL = 25 mg/kg/day LOAEL = 75/50 mg/kg/day (M/F) based on decreased body weight and testicular atrophy.
870.3150	90-Day oral toxicity (dog)	45029901 (1992) Acceptable/guideline 0, 1, 5, or 15 mg/kg/day	NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on decreased body weight, body weight gain, and food consumption/efficiency.
870.3700a	Prenatal developmental (rat) (CrI:CD® (SD) BR from Charles River Laboratories Inc., Portage, Michigan)	45029911 (1989) Acceptable/guideline 0, 3, 10, 40 mg/kg/d	Maternal NOAEL = 10 mg/kg/day LOAEL = 40 mg/kg/day based on findings (as early as GD 6-9) of decreased body weight gain, food intake, and food efficiency. Developmental NOAEL = 40 mg/kg/day LOAEL = > 40 mg/kg/day.
870.3700b	Prenatal developmental (rabbit)	45029912 (1990) Unacceptable/guideline 0, 3, 13, 60 mg/kg/d	Maternal NOAEL = 60 mg/kg/day LOAEL = > 60mg/kg/day based on lack of findings. Developmental NOAEL = 60 mg/kg/day LOAEL = > 60 mg/kg/day based on lack of findings.

870.3800	Reproduction and fertility effects (rat) (CrI:CD® (SD) BR from Charles River Breeding Laboratories, Raleigh, NC)	46684001 (1991) Acceptable/guideline 0, 1, 5, or 25 mg/kg/d	Parental/Systemic NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on excessive salivation and decreased body weight/weight gain and food intake. Reproductive NOAEL = 25 mg/kg/day LOAEL = >25 mg/kg/day. Offspring NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on decreased weight gain during lactation.
870.4300	Chronic toxicity/ Carcinogenicity Rat (Fischer 344 from Taconic Laboratory Animals and Services, Germantown, N.Y)	45029907 (1992) Acceptable/guideline 0, 10, 100, 200, or 400/450 (males/females) ppm M: .0.0, 0.46, 4.5, 9.2, and 18.3 mg/kg/d F: 0.0, 0.57, 5.7, 11.5, and 25.9 mg/kg/d	NOAEL = 9.2 mg/kg/day LOAEL = 18.3 mg/kg/day based on decreased body weight, body weight gain, and food consumption/efficiency.
870.4100	Chronic toxicity (dog)	45029906 (1993) Acceptable/guideline 0, 1, 5, or 12 mg/kg/d	NOAEL = 5 mg/kg/day LOAEL = 12 mg/kg/day based on decreased body weight, body weight gain, and food consumption/efficiency.
870.4200	Carcinogenicity (hamster)	45029913 (1992) Acceptable/guideline 0, 2, 15, or 30/35 (males/females) mg/kg/d	NOAEL = 2/15 mg/kg/day (M/F) LOAEL = 15/35 mg/kg/day (M/F) based on decreased body weight (F) and body weight gain (M/F)-food consumption was not recorded. No evidence of carcinogenicity
870.5100	Gene Mutation Bacterial reverse mutation assay	44742909 (1989) Acceptable/guideline	Negative ± S9 up to 3000 µg/mL in the absence of cytotoxicity with precipitation above this concentration.
870.5300	Gene Mutation Mammalian cell culture (mouse lymphoma cells)	44742908 (1989) Acceptable/guideline	Negative –S9 severely cytotoxic at concentrations up to 10 µg/mL Positive + S9 at concentrations (up to 12 µg/mL) that were severely cytotoxic (10-20% survival)
870.5375	Cytogenetics Chromosomal aberrations (CHO cells)	44742907 (1989) Acceptable/guideline	Negative ± S9 for clastogenic/aneugenic activity up to concentrations that reduced cell survival by ≈50% (1 µg/mL-S9; 60 µg/mL+S9). Compound precipitation was evident at levels ≥ 24 µg/mL +/-S9.

870.5395	Micronucleus Assay (mouse)	44742904 (1989) Acceptable/guideline	Negative for clastogenic/aneugenic activity in mouse bone marrow up to the highest dose tested in males/females (1600/1200 mg/kg, repeated on two days). In a preliminary study, the median lethal doses (MLD) were 3191/ 2430 mg/kg (M/F).
870.5915	<i>In vivo</i> SCE Assay (mouse)	44742905 (1989) Unacceptable/guideline (each data point had 3 males which is lower than the guideline recommended 5/sex/dose)	Negative in this cytogenetic assay (no increase in SCE) of bone marrow from male CD-1 mice treated with doses up to levels that produced death (2000 mg/kg).
870.5550	<i>In vitro</i> UDS Assay	44742906 (1989) Acceptable/guideline	Negative up to cytotoxic concentrations (≥ 0.5 to 1.0 $\mu\text{g/mL}$).
No Guideline	<i>In viro</i> UDS Assay	45029908 (1989) Acceptable/non-guideline	Negative for DNA damage and repair in this <i>in vivo/in vitro</i> test system up to the maximum tolerated dose (600 mg/kg).

870.7485	Metabolism and pharmacokinetics (species)	44742901 (1992) Unacceptable/guideline	<p>Irrespective of dose, most of an orally administered radiolabeled fenazaquin was in rat excreta (89.5-107.7%) at 168 hours with approximately 20% of the radiolabel in urine. After initial uniform distribution, about 0.5-1.6% of the dose was in the carcass and below 0.04% of the dose in each tissue. There was no radiolabel in the expired air and no evidence for bioaccumulation. Based on excretion and tissue residue data, bioavailability is conservatively estimated at about 20% of an administered dose.</p> <p>Non-metabolized fenazaquin was higher in feces (1.0-15.0% of administered dose) than in urine (below 0.5% of dose) and some of the major metabolites were identified including AN-1 (urine) in addition to the fecal metabolites F-1, F-2 and F3. The metabolic pathway of fenazaquin involved cleavage of the ether bond, resulting in the formation of the respective alcohol (4-OH quinazoline metabolite) and carboxyl acid (AN-1) derivatives. Other biotransformation reactions included oxidation of one of the methyl groups on the alkyl side chain to produce either an alcohol (F-1) or carboxylic acid (F-2) metabolites. Finally, hydroxylation at the O-ether alkyl moiety of F-1 or the 2-position of the quinazoline ring of F-2 resulted in F-1A and F-3 metabolites, respectively.</p>
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Non-guideline	Special studies: Potential to induce hepatic hypertrophy and peroxisome acyl-CoA oxidase activity in mice	44742903 (1993) Acceptable/non-guideline	Fenazaquin and several of its analogs (with varying susceptibilities to metabolism of the ether bond or the alkylbenzene substituents) were assessed for their ability to increase liver peroxisomal fatty acyl-CoA oxidase (FAO, a marker of peroxisomal proliferation) and relative liver weight in groups of five CD-1 female mice. The FAO peroxisomal activity data indicate that oxidation of the t-butyl substituent on the alkylbenzene moiety (to the corresponding carboxylic acid) of fenazaquin and related compounds appears to be the critical step for hepatocellular peroxisome proliferation.
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4. Hazard Characterizations

a. Acute Exposure

Fenazaquin is acutely toxic when administered orally in rats (LD50 = 134/138 mg/kg in males/females). No data were made available on acute toxicity by other routes of exposure.

b. Repeated Exposure

The **major findings** following repeated oral administration in rats, hamsters and dogs were decreases in **body weight, body weight gain, food intake, and food efficiency**. With one exception, these findings occurred at the highest tested dose (≤ 35 mg/kg/day) in each of the subchronic or chronic toxicity studies.

In the 90-day hamster study which used doses up to 150 (males) and 100 (females) mg/kg/day, the magnitude of the decrease was dose-dependent for body weight (8-23% and 19-28% in males and females, respectively) and body weight gain (16-74% and 39-61% in males and females, respectively); however, due to food spillage problems, food consumption and efficiency data were not presented. In the same study, testicular atrophy (dose-dependent decreased weight and hypospermatogenesis) and decreased prostate weight/relative weight were also evident at 75 and 150 mg/kg/day.

At the doses used (≤ 35 mg/kg/day) in all remaining subchronic and chronic toxicity studies, there were no organ specific toxicity findings.

Similar effects on body weight/weight gain and food intake/efficiency were also identified in parental animals of the **rat developmental and reproduction studies and in the offspring of the reproduction rat study**. There were no developmental findings in the rat study (up to 40 mg/kg) and no parental or developmental findings of any kind

up to 60 mg/kg/day in the rabbit developmental study.

There are **no specific neurotoxicity studies**, including acute-, subchronic-, or developmental. There is no clear evidence of consistent neurotoxicity findings in the available toxicity studies. Findings of excessive salivation in the rat reproduction toxicity study are unlikely to be a sign of neurotoxicity since the chemical is not known to have a neurotoxic mode of action and no similar clinical findings were reported in the 90-day or chronic/carcinogenicity studies.

Fenazaquin appears to increase peroxisomal proliferation in rats and mice but hamsters were resistant since peroxisomal beta oxidation was not increased in the 90-day hamster study.

A supplementary report (MRID 44742910) was provided as justification for using the hamster as an appropriate animal model for fenazaquin. Based on the report, the NOAEL in a three-month feeding study in mice was 150 mg/kg/day in males and > 600 mg/kg/day in females and the only effect observed was a decrease in body weight gain. (The actual 90-day mouse study was not made available to EPA.) In the similar rat and hamster toxicity studies, the NOAEL was 10 and 25 mg/kg/day, respectively, based on decreased body weight gain (in addition to hamster testicular atrophy) thus showing that the rat and hamster were more sensitive to the effects of fenazaquin than mice. Additionally, a comparative pharmacokinetic analysis showed that peak plasma levels were not proportional to dose in both male and female mice, but area under the curve (AUC) was well correlated to dose. Peak plasma levels were observed between 0.5-4 hours post dosing. Plasma elimination rate of fenazaquin was dose dependent and became slower at doses ≥ 300 mg/kg. Conversely, rat peak plasma level was reached in 8 hours and AUC was proportional to dose while elimination was independent of dose. Results from the pharmacokinetics study indicated similar pharmacokinetics of radiolabeled fenazaquin in the hamster at doses between 5 and 125 mg/kg with peak plasma levels being reached in 2 hours.

The hamster was chosen over the mouse for a second carcinogenicity study based on findings in the hamster of slower elimination kinetics and greater systemic toxicity. Because of the high tolerance of the mouse in regard to effect on body weight gain, the laboratory chose to use Syrian golden hamsters as a secondary rodent model, along with rats.

5. Food Quality Protection Act Considerations

Based on the hazard and exposure data, the fenazaquin risk assessment team has recommended that the FQPA Safety Factor be reduced to 1X because:

- a. there is an adequate toxicity database for the food import tolerance on fenazaquin;
- b. the exposure data are complete or are estimated based on data that reasonably account for potential exposures;
- c. there is no evidence of susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the two-generation

- rat reproduction study;
- d. there are no residual uncertainties concerning pre- and postnatal toxicity;
- e. the dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100% CT information for all commodities and, therefore, will not be underestimated;
- f. there is no potential for dietary drinking water exposure; and
- g. there are no residential uses.

6. Classification of Carcinogenic Potential

EPA reviewed the carcinogenicity study in hamsters, as well as the carcinogenicity study conducted in rats, the mutagenicity studies, and discussed the possible carcinogenic mode of action of fenazaquin. Based on the weight of evidence of these studies, and in accordance with the 2005 Guidelines for Carcinogen Risk Assessment, the members concluded that the negative hamster findings along with the negative tumor findings in the 24-month rat study and negative mutagenicity findings support a cancer classification of “**Not likely to Be Carcinogenic to Humans**” for fenazaquin. EPA concluded that the carcinogenicity study in hamsters is “Acceptable/Guideline” and satisfies the guideline requirement for a carcinogenicity study [OPPTS 870.4200; OECD 451] in hamsters. Despite the enteritis and administration of antibiotics, the study is considered acceptable based on the adequacy of dosing based on evidence of systemic toxicity, acceptable survival rate at 17 months, and lack of evidence for tumorigenicity in two species, hamsters and rats.

7. Toxicological Doses and Endpoints

Table 5 summarizes the toxicological doses and endpoints for use in the fenazaquin dietary assessment.

Table 5. Summary of Toxicological Doses and Endpoints for Fenazaquin for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations, including Females 13-49 and Infants/Children)	NOAEL= 10 mg/kg/day	UF _A = 10 x UF _H = 10 x FQPA SF= 1 x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Rat developmental toxicity LOAEL = 40 mg/kg/day based on findings (as early as GD 6-9) of decreased body weight gain, food intake, and food efficiency.
Chronic Dietary (All Populations)	NOAEL= 5 mg/kg/day	UF _A = 10 x UF _H = 10 x FQPA SF= 1 x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Rat two-generation toxicity study LOAEL = 25 mg/kg/day based on excessive salivation and decreased body weight/weight gain and food intake.
Short- and Intermediate-Term Incidental Oral (1-30 days; 1-6 months)	These exposure scenarios do not apply to this risk assessment because there are no proposed registered residential uses of fenazaquin.			
Short-, Intermediate-, and Long-Term Dermal (1-30 days; 1-6 months)	These exposure scenarios do not apply to this risk assessment because there are no proposed registered residential or occupational uses of fenazaquin.			
Short-, Intermediate-, and Long-Term Inhalation (1-30 days; 1-6 months)	These exposure scenarios do not apply to this risk assessment because there are no proposed registered residential or occupational uses of fenazaquin.			
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. N/A = not applicable.

8. Dietary Exposure and Risk

Acute and chronic dietary risk analyses were made with the DEEM-FCID™ model to form a conservative evaluation of exposure for fenazaquin. The acute dietary analysis made at the 95th percentile indicate risk estimates are reasonably below the 100% of the aPAD threshold level of concern for each population subgroup. For the most highly exposed population subgroup, children 1-2 years of age, acute dietary risk was estimated to be 48% of the aPAD with an exposure of 0.047574 mg/kg/day. In conjunction, chronic analysis yielded risk estimates well below the 100% of the cPAD threshold level

of concern for each population subgroup. Likewise, for children 1-2 years of age, chronic dietary risk proved to be 25% of the cPAD with an exposure of 0.012690 mg/kg/day. Table 6 summarizes the results of the acute and chronic dietary assessments.

Table 6. Summary of Dietary Exposure and Risk for Fenazaquin						
Population Subgroup	Acute Dietary (95.0 Percentile)		Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% aPAD ¹	Dietary Exposure (mg/kg/day)	% cPAD ¹	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	0.014857	15	0.003092	6.2	NA ²	NA
All Infants (< 1 year old)	0.011808	12	0.004650	9.3	NA	NA
Children 1-2 years old ³	0.047574	48	0.01269	25		
Children 3-5 years old	0.034100	34	0.009100	18		
Children 6-12 years old	0.020877	21	0.004865	9.7		
Youth 13-19 years old	0.015223	15	0.002967	5.9		
Adults 20-49 years old	0.010338	10	0.001967	3.9		
Adults 50+ years old	0.008336	8.3	0.002020	4.0		
Females 13-49 years old	0.011299	11	0.002177	4.4		

¹ Report %PADs to 2 significant figures.

² Not Applicable (NA).

³ The values for the highest exposed population for each type of risk assessment should be bolded.

9. Anticipated Residue and Percent Crop Treated (%CT) Information

EPA assumes that fenazaquin residues are in/on all registered food commodities at tolerance levels and that 100% of all RACs are treated.

10. Aggregate Risk Assessments and Risk Characterization

There are no proposed or existing residential uses for fenazaquin. The proposed use is limited to apples, pears and citrus fruits exported to the U.S. only. The exposure/risk assessment is limited to dietary food only (**no aggregate**).

11. Occupational Exposure and Risk

As this assessment is for an import tolerance, the anticipated exposure route for the US population is via the diet (food only). Thus, occupational exposure risk assessments for incidental oral, dermal, and inhalation routes of exposure are not required.

12. Proposed and Established Tolerances

Table 7 lists the proposed and established tolerance for Fenazaquin. EPA established no tolerances for livestock commodities as EPA does not expect any residues in those commodities.

Table 7. Tolerance Summary for Fenazaquin.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
Apple	0.2	0.2	Adequate data are available
Pear	0.2	0.2	Adequate data are available
Citrus fruits	0.5	0.5	Adequate data are available. <i>Fruit, citrus, group 10, except grapefruit</i>
Citrus oil	None	10	Based on HAFT residues of 0.40 ppm and an average processing factor of 25x for citrus oil, a separate tolerance is required for <i>Citrus, oil</i>
Apple, pomace, wet	None	None	Although residues were shown to concentrate in wet apple pomace (1.7x) and dried citrus pulp (3.2x), tolerance are not required for these feedstuff as they are unlikely to be imported.
Citrus, pulp, dried	None	None	

13. Data Gaps

A. Current Import Tolerances

1. Additional storage stability data are required on apples to support the sample storage intervals from the tests conducted on pears and apples in Argentina during 1993/94 and on apples in Chile during 1995. Gowan must submit data demonstrating the stability of fenazaquin in frozen apples for intervals up to 25 months.
2. Gowan must submit a reference standard for fenazaquin to the National Pesticide Standards Repository.

B. Future Tolerances

1. Radio validation data demonstrating the extraction efficiency of the proposed single analyte enforcement methods were not submitted. However, the available data indicate fenazaquin tolerances may be enforced using the existing FDA Multiresidue Methods in PAM, Vol I. Testing of fenazaquin through the multiresidue methods indicated that fenazaquin was adequately recovered from whole oranges and from orange oil. Radiovalidation data for the single analyte methods should be submitted with future petitions.

2. For future petitions, the following information is needed for each of the ILV studies: (i) a description of the number of trials required to obtain the reported recovery values; (ii) a description of any problems encountered and a written description of any changes or modifications that were made to the method during the ILV; (iii) discussion of any steps considered critical; (iv) time required for analysis of one set of samples; and (v) details of communications between the independent laboratory and the method developers or others familiar with the method.
3. Gowan must develop and validate (ILV and radiovalidation) an analytical enforcement method capable of quantitating parent fenazaquin and its dimer prior to conducting crop field trial studies to support any new uses.

14. Labeling Deficiencies

- Although a general summary of the use directions on apples, pears and citrus fruits was provided, additional information is required detailing the maximum allowed use rates and minimum PHIs allowed for apples, pears and citrus fruits in each country in which these uses are allowed. Representative labels (and translations) should be submitted for each crop from the major growing regions (Europe, South America, and Asia).

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

APPENDIX I:

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
%CT	Percent crop treated
DAT	Days after treatment
DEEM-FCID	Dietary Exposure Evaluation Model - Food Consumption Intake Database
DNA	Deoxyribonucleic acid
DNT	Developmental neurotoxicity
DIT	Developmental immunotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GLN	Guideline Number
LC₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOC	Level of Concern

LOD	Limit of Detection
LOQ	Limit of quantitation
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number), EPA's system of recording and tracking studies submitted
MTD	Maximum tolerated dose
NA	Not Applicable
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NPDES	National Pollutant Discharge Elimination System
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/	
EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
µg	micrograms
µg/L	Micrograms Per Liter
µL/g	Microliter per gram
USDA	United States Department of Agriculture
WPS	Worker Protection Standard

APPENDIX II:

Citations Considered to be Part of the Data Base Supporting the Registration of

Fenazaquin

MRID	Citation Reference
43798700	DowElanco (1995) Submission of Toxicology Data in Support of the Registration of Fenazaquin. Transmittal of 2 Studies.
43798701	Francis, P.; Boss, S.; Gries, C. (1992) A Carcinogenicity Study in Syrian Golden Hamsters Administered EL-436 (Compound 193136) Orally for 18 Months: Lab Project Number: T6K TCHMST AM: HC0307: H00390. Unpublished study prepared by Lilly Research Labs. 2781 p.
43798702	Francis, P. (1995) Supplement to the "Carcinogenicity Study in Syrian Golden Hamsters Administered EL-436 (Compound 193136) Orally for 18 Months": A Review of the Historical Incidence of Adrenocortical Adenomas in Hamsters: Lab Project Number: HC0307: H00390: H00790. Unpublished study prepared by Lilly Research Labs. 12 p.
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